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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/748,783	12/26/2000	David R. Goodlett	P-IS 4369	3333

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CAMPBELL & FLORES LLP
4370 LA JOLLA VILLAGE DRIVE
7TH FLOOR
SAN DIEGO, CA 92122

EXAMINER

MAHATAN, CHANNING

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/748,783

Applicant(s)

GOODLETT, DAVID R.

Examiner

Channing S. Mahatan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-47 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.

- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) 4 Sheets
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Attachment for PTO-948.

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DETAILED ACTION

ART UNIT DESIGNATION

The Group and/or Art Unit designated for this application has changed. Applicant(s) are hereby informed that future correspondence regarding this application should be directed to Group Art Unit 1631.

Restriction/Election Requirement

FIRST SPECIE ELECTION REQUIREMENT

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie IA. ion selection, claims 1-5, 7-16, 18-23, and 37-47

Specie IB. absence of ion selection, claims 1-47

The above species are directed to distinct inventions because of the selection criteria utilizing mass spectrometry to determine the mass of a polypeptide. Further, applicant discloses within the specification (page 26, lines 19-31) characteristics and method steps distinctly distinguishing ion selection versus absence of ion selection. Thus, the search burden for the above species are non-overlapping thus supporting this specie election requirement due to an undue search burden if the species were examined together via two separate searches.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, 7-16, 18-23, and 37-47 are generic to the above Species IA and IB.

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SECOND SPECIE ELECTION REQUIREMENT

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie IIA. identification of a polypeptide without quantitation of said polypeptide in a sample, claims 1, 2, 4-11, 24, 25, 27-38, and 40-47.

Specie IIB. identification of a polypeptide with quantitation of said polypeptide in a sample, claims 1-47

The above species are directed to distinct inventions because of the selection criteria utilizing mass spectrometry to determine the mass of a polypeptide. The step of identifying a polypeptide without quantification of the analyte is considered distinctly different from identifying a polypeptide with quantification as observed in the art. Thus, the search burden for the above species are non-overlapping thus supporting this specie election requirement due to an undue search burden if the species were examined together via two separate searches.

Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4-11, 24, 25, 27-38, and 40-47 are generic to the above Species IIA and IIB.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction/election for examination purposes as indicated is proper.

ELECTION BY TELEPHONE

During a telephone conversation with Deborah Cadena on 21 February 2002 a provisional election was made with traverse. Applicant elected Specie IB (absence of ion selection) and Specie IIB (identification of a polypeptide with quantitation of said polypeptide). Affirmation of this election must be made by applicant in replying to this Office action.

Claims herein under examination are claims 1-47.

OBJECTION BY DRAFTSMAN

Applicant(s) is (are) hereby notified that the required timing for correction of drawings has changed. See the last 6 lines on the sheet, which is attached, entitled "Attachment for PTO-

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948 (Rev. 03/01 or earlier)". Due to the above notification Applicant is required to submit drawing corrections with the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

OBJECTION TO CLAIM

Claim 12 is objected to because of the following informality: dependency to claim 13. A series of singular dependent claims is permissible in which a dependent claim refers to a preceding claim which, in turn, refers to another preceding claim. A claim which depends from a dependent claim should not be separated by any claim which does not also depend from said dependent claim. It should be kept in mind that a dependent claim may refer to any preceding independent claim. Appropriate correction is required.

Provisional Obviousness-Type Double Patenting

The non-statutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 U.S.P.Q. 2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); and, *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969).

A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground

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provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 1-5, 8-16, 18-23, and 37-47 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 and 32-43 of co-pending Application No. 09/748,793. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims define an invention which is a method of identifying a polypeptide with such similarity making the inventions have overlapping embodiments. A subset of parent polypeptides in claim 1 of 09/748,783 is reasonably interpreted to include a single polypeptide as cited in claim 1 of 09/748,793. In addition, the mass of the subset (single) polypeptide in 09/748,783 is suggested as a characteristic in claim 12 of 09/748,793 which depends from claim 1 of 09/748,793 and thus suggests characteristics in said claim 1 of 09/748,793.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims Rejected Under 35 U.S.C. § 112 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

VAGUE AND INDEFINITE

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Claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 7-11, 13, 18-22, and all claims dependent therefrom are vague and indefinite as to which fragments are determined at the specified accuracy in ppm. Applicant can resolve this issue by particularly pointing out which fragments are being determined: 1) all fragments are determined at an accuracy level in ppm or 2) a selection of certain fragments are determined at an accuracy level in ppm.

Claims Rejected Under 35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-12, 24, 25, 27-38, and 40-47 are rejected under 35 U.S.C. § 102(b) as being anticipated by Bruce et al.

Bruce et al. teaches a method of utilizing Fourier transform ion cyclotron resonance mass spectrometry (FTICR-MS) to analyze polypeptide mixtures resulting from proteolytic digestion (abstract). FTICR-MS provides the highest combination of simultaneous mass measurement accuracy, resolution, and sensitivity (p 2596, column 1, lines 31-35). Bruce et al. states that routine parts-per-million mass accuracy (ranges between 0.7 ppm to more than 100 ppm, Easterling et al., p 626, column 1, lines 34-39; p 627, column 1, lines 4-34; p 630, column 2,

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lines 32-43; Table 1 and 2) may be obtained for high-mass ions with MALDI-FTICR (p 2596, column 1, lines 37-38). Identification of peptides from the resulting masses are determined through the comparison to a generated table of masses based on all possible proteolysis products for the protein, also indication to annotated amino acid sequence (p 2597, column 1, lines 7-22). The said generated table of masses is the "annotated polypeptide index" as in the instant claims.

Claims 1-10, 12-21, 23-31, 33-42, 44-47 are rejected under 35 U.S.C. § 102(a) as being anticipated by Goodlett et al. (IDS, Goodlett et al. Anal. Chem. 15 March 2000, Vol. 72, pages 1112-1118).

Goodlett et al. teaches a method of protein identification by using electrospray ionization-Fourier transform ion cyclotron resonance mass spectrometry and sequence database searching (Abstract). The authors provide reasons as to the disadvantages of selection of peptide ions from a mixture of analytes, and state "the more accurately peptide masses are measured and the more peptide masses are detected from the same protein, the more conclusively the protein can be determined" (p 1113, column 1, lines 11-22). This absence of ion selection criteria is then applied to the experiment with varying mass accuracies, ranging from 0.1 ppm to 10.0 ppm (Figure 1). Goodlett et al. describe an annotated polypeptide index with database characteristics comprising molecular weight, cleavage specificity, presence of rare amino acids, protein name, peptide isobars, and error in ppm (Table 1 and p 1113, column 2, lines 21-25). Mass spectra were acquired in a single stage of mass spectrometry using electrospray ionization-Fourier transform ion cyclotron resonance mass spectrometry (ESI-FTICR MS) (p 1113, column 2, lines 33-36). Proteins were identified and quantitated by the accurately measured masses of single

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IDeNt-labeled peptides using the same FTICR MS data set used for the mass mapping analysis (p 1117, column 1, lines 17-40). Thus, Goodlett et al. clearly anticipates the claimed invention.

Claims Rejected Under 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-47 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bruce et al. in view of Gygi et al. (IDS, Gygi et al. Nat. Biotechnol., 17 October 1999, Vol. 17, pages 994-999).

Bruce et al. teaches the identification of polypeptides by Fourier transform ion cyclotron resonance mass spectrometry (FTICR-MS). Bruce et al. fails to provide the elements of quantitation of the polypeptides. Gygi et al. describes an approach for the accurate quantification and concurrent sequence identification of individual proteins within complex mixtures in a single automated operation (Abstract and p 995, column 2, lines 1-2). The ICAT strategy (Figure 2 and p 995, column 1-2, lines 1-8 and 1-2, respectively) provides a broadly applicable solution to quantitative proteome analysis, particularly mass spectrometry (p 998, column 2, lines 43-65).

Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the method of quantitating the proteins identified in a single automated operation, as taught by Gygi et al. with Bruce et al. method of identifying polypeptides by FTICR-MS. The motivation to utilize the single automated operation described by Gygi et al would increase efficiency over separate operations.

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Claims 1-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bruce et al. in view of Goodlett et al. (IDS, Goodlett et al. Anal. Chem. 15 March 2000, Vol. 72, pages 1112-1118).

Bruce et al. and Goodlett et al. teach the identification of polypeptides by Fourier transform ion cyclotron resonance mass spectrometry (FTICR-MS). Bruce et al. fails to provide the elements of quantitation of the polypeptides, while Goodlett et al. fails to describe that a wide range of mass accuracies may be performed in FTICR-MS. Goodlett et al. cites Bruce et al. (p 1113, column 2, bottom) leading one of ordinary skill in the art to search for the cited reference.

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention was made to include the method of identification and quantitation of the polypeptide by FTICR-MS, as taught by Goodlett et al. (refer to rejection under 102(a)), with Bruce et al. the method of identification of a polypeptide utilizing a wide range of mass accuracies by FTICR-MS (refer to rejection under 102(b)).

Appropriate Correction Is Required.

No Claims Are Allowed.

EXAMINER INFORMATION

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 C.F.R. § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Channing S. Mahatan whose telephone number is (703) 308-2380. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael P. Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, William Phillips, whose telephone number is (703) 305-3482 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

Date: *March 13, 2002*

Examiner Initials: *CSM*

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER